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## Contents: Biosafety in Research

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

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### Section

### Overview of Content (see section for full process)

#### [Introduction](#)

#### [1. Planning to Use Biological Materials](#)

- Determine characteristics and potential hazards of the biological materials.
- Determine if work involves recombinant DNA or regulated etiologic agents.
- Obtain approvals.

#### [2. Acquiring Biological Materials and Establishing Containment](#)

- After obtaining approval, procure biological materials.
- Comply with shipping and receiving requirements.
- Establish containment based on characteristics and potential hazards identified during risk assessment.

#### [3. Storing and Using Etiologic Agents](#)

- Authorize and supervise use of all etiologic agents.
- Handle agents based on characteristics and potential hazards identified during risk assessment.
- Upon request, inform Institutional Biosafety Committee on the status of the regulated etiologic agent.

#### [4. Disposing of Biological Materials](#)

- Dispose of nonpathogenic biological liquid and solid waste appropriately.
- Chemically disinfect pathogenic biological liquid waste.
- Dispose of pathogenic biological solid waste according to requirements.
- Decontaminate reusable labware.

#### [Definitions](#)

**Exhibits**[Biosafety Organizational Reviews and Approvals](#)[Biosafety Review Procedure Flowchart](#)[Special Microbiological Practices for Biosafety Level 2 Microorganisms](#)[Standard Practices for Biosafety Level 1 Microorganisms](#)**Forms**[Etiologic Agent Form](#)[Recombinant DNA Form](#)

## Training Requirements and Reporting Obligations

This subject area does not contain training requirements.

This subject area does not contain reporting obligations.

## References

42 CFR 72, Additional Requirements for Facilities Transferring or Receiving Select Agents

[American Biological Safety Association, Risk Group Classification for Infectious Agents](#)[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC)[Bloodborne Pathogens](#) Subject Area[Liquid Effluents](#) Subject Area[NIH Guidelines, Appendix E. Certified Host-vector Systems](#)[NIH Guidelines, Appendix G. Physical Containment](#)[NIH Guidelines, Appendix I. Biological Containment](#)[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)[Office of Research Administration](#)[Regulated Medical Waste Management](#) Subject Area[Transfer of Hazardous Materials Onsite](#) Subject Area[Transportation of Hazardous Materials Offsite](#) Subject Area[Work Planning and Control for Experiments and Operations](#) Subject Area

## Standards of Performance

All staff and guests shall comply with applicable Laboratory policies, standards, and procedures, unless a formal variance is obtained.

All staff and users shall identify, evaluate, and control hazards in order to ensure that work is conducted safely and in a manner that protects the environment and the public.

All staff and users shall ensure that they are trained and qualified to carry out their assigned responsibilities, and shall inform their supervisor if they are assigned to perform work for which they are not properly trained or qualified.

## Management System

This subject area belongs to the **Worker Safety and Health** management system.

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**Introduction: Biosafety in Research**Effective Date: **December 2002**Point of Contact: [Biosafety Subject Matter Expert](#)

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This subject area describes the procedures users of biological materials must follow to perform research at BNL. In this subject area, biological materials include human and primate blood, blood components or tissue, microorganisms, such as bacteria, protozoa, mycoplasma, and viruses, and other potentially infectious material such as recombinant DNA. This subject area also serves as an essential component of the BNL work planning and control requirements for work with biological materials.

This subject area describes the processes for all staff who work with or supervise work with biological materials to follow. It applies to

- BNL staff and non-BNL staff;
- BNL staff working off-site, if the off-site location does not have their own federal, state, and/or local requirements.

Excluded from this subject area are


- Environmental biohazards (i.e., microorganisms found in buildings and outdoor settings or animal carriers of diseases, such as rabies, Hantavirus, histoplasmosis, and Lyme Disease).

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# 1. Planning to Use Biological Materials

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

## Applicability

This information applies to BNL staff and non-BNL staff who acquire, manage, use, or supervise users of biological materials.

## Required Procedure

Contact the Institutional Biosafety Committee, the Industrial Hygiene Group, or another ES&H professional, if you need assistance with this procedure.

Refer to the exhibit [Biosafety Review Procedure Flowchart](#) for an overview of the biosafety review process.

<b>Step 1</b>	<p>The Principal Investigator/Responsible Person (PI/RP) determines the characteristics and potential hazards of the biological materials to be used by doing the following:</p> <ul style="list-style-type: none"><li>• Conducting a Biological Risk Assessment. For assistance in conducting a risk assessment, see <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a> or <a href="#">NIH Guidelines for Research Involving Recombinant DNA Molecules</a>, National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC).</li><li>• Documenting the assessment in an Experimental Safety Review (ESR), unless it is already covered by an existing one. See the section <a href="#">Experimental Safety Review</a> in the <a href="#">Work Planning and Control for Experiments and Operations</a> Subject Area for information on an ESR.</li></ul> <p><b>Note:</b> The Experiment Review Coordinator should include other organizations in the review process as applicable. See the exhibit <a href="#">Biosafety Organizational Reviews and Approvals</a>.</p>
<b>Step 2</b>	<p>The PI/RP determines if work will involve the following:</p>

	<ul style="list-style-type: none"> <li>• Recombinant DNA. See the <a href="#">NIH Guidelines for Research Involving Recombinant DNA Molecules</a> (NIH Guidelines). If so, then submit a <a href="#">Recombinant DNA Form</a> to the Institutional Biosafety Committee (IBC).</li> <li>• Regulated etiologic agents. If so, then submit an <a href="#">Etiologic Agent Form</a> to the IBC.</li> </ul>
<b>Step 3</b>	<p>The PI/RP must have pre-approval from the Department Chair/Division Manager (through the Experimental Safety Review process) before submitting either form to the IBC. See the section <a href="#">Experimental Safety Review</a> in the <a href="#">Work Planning and Control for Experiments and Operations</a> Subject Area for information. The IBC sends approval and/or comments to the PI/RP and Experiment Review Coordinator. The Department Chair/Division Manager gives final approval after the IBC grants approval.</p> <p>Work with animal and/or human subjects requires additional approval, see the <a href="#">Office of Research Administration</a> for information.</p> <p>Work with infectious agents of livestock also may require additional approval and import permits, see the Office of Research Administration (ORA) for more information.</p>
<b>Step 4</b>	<p>The PI/RP determines if the material is a bloodborne pathogen. If the material is a bloodborne pathogen, the PI/RP follows the required procedures in the <a href="#">Bloodborne Pathogens</a> Subject Area.</p>
<b>Step 5</b>	<p>The PI/RP determines if the biological material is nonhazardous, justifies the risk in the ESR, and obtains approval from the Department Chair/Division Manager.</p> <p>If the material does represent a potential biohazard (e.g., <i>Pfisteria</i>, <i>B. Burgdorferi</i>), the Experiment Safety Review Coordinator determines if Institutional Biosafety Committee Approval is required.</p>

## References

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC)

[Bloodborne Pathogens](#) Subject Area


[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

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## 2. Acquiring Biological Materials and Establishing Containment

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

### Applicability

This information applies to BNL staff who acquire, store, relocate, and use biological materials.

### Required Procedure

Work involving biological materials must be done in the appropriate containment conditions. Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Currently four Biosafety Levels (1-4) define the level of containment necessary to protect personnel and the environment. A Biosafety Level 1 (BSL-1) is the least restrictive, while Biosafety Level 4 (BSL-4) requires a special containment laboratory or facility. There are no approved BSL 3 or BSL 4 containment facilities at BNL.

Contact the Institutional Biosafety Committee, the Industrial Hygiene Group, or another ES&H professional, if you need assistance with this procedure.

Acquiring Biological Materials and Establishing Containment is divided into two subsections:

[2.1 Procuring Biological Materials](#)

[2.2 Containment of Biological Materials](#)

### 2.1 Procuring Biological Materials

<b>Step 1</b>	The Principal Investigator/Responsible Person (PI/RP) or designee can procure biological materials on a credit card or via a Web Requisition. However, the PI/RP must maintain an inventory of regulated agents.
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	Do not procure biological materials until you have approval to use them. See the section <a href="#">Planning to Use Biological Materials</a> .
<b>Step 2</b>	<p>Before receiving any etiologic agents, the PI/RP contacts the <a href="#">Transportation Safety Department/Division Point of Contact</a> or <a href="#">Transportation Safety Officer</a> to determine if the material is regulated, and must comply with the <a href="#">Transfer of Hazardous Materials Onsite</a> Subject Area and the <a href="#">Transportation of Hazardous Materials Offsite</a> Subject Area.</p> <p>For additional information on shipping and receiving of biological materials, see these subject areas and <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a>, National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC).</p>
<b>Step 3</b>	<p>Before transporting (on-site or off-site) any regulated etiologic agents, the PI/RP contacts the <a href="#">Transportation Safety Department/Division Point of Contact</a> or <a href="#">Transportation Safety Officer</a> to determine if the material is regulated and must comply with Department of Transportation and the <a href="#">Transfer of Hazardous Materials Onsite</a> Subject Area and the <a href="#">Transportation of Hazardous Materials Offsite</a> Subject Area.</p>

## 2.2 Containment of Biological Materials

<b>Step 1</b>	<p>The PI/RP establishes containment based on the characteristics and potential hazards identified during risk assessment.</p> <ul style="list-style-type: none"> <li>• <b>For Biosafety Level 1 &amp; 2</b>, follow the Standard Practices listed in <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a>, National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC). See the exhibits <a href="#">Standard Practices for Biosafety Level 1 Microorganisms</a> and <a href="#">Special Microbiological Practices for Biosafety Level 2 Microorganisms</a> for information.</li> <li>• <b>There are no approved BSL 3 or BSL 4 facilities at BNL.</b></li> <li>• For human blood or tissue, see the <a href="#">Bloodborne Pathogens</a> Subject Area.</li> <li>• <b>For Recombinant DNA</b>, follow the requirements in the <a href="#">NIH Guidelines for Research Involving Recombinant DNA Molecules</a>.</li> <li>• <b>For USDA Hazard (potential risks to plants and animals)</b>, a USDA Animal and Plant Health Inspection Service (APHIS) permit may be required. Contact your <a href="#">Environmental Compliance Representative</a> for assistance.</li> <li>• <b>For Animals and Human Subjects</b>, contact the <a href="#">Office of Research Administration (ORA)</a>.</li> </ul> <p><b>Note:</b> The PI/RP should discuss and get approval for biosafety level practices during the Experimental Safety Review.</p>
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## References

[Bloodborne Pathogens](#) Subject Area

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC)

[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

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## 3. Storing and Using Etiologic Agents

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

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### Applicability

This information applies to BNL staff and non-BNL staff who transport, use, and/or store etiologic agents.

### Required Procedure

All etiologic agents must have a risk assessment to identify the appropriate biosafety level practices (see the section [Planning to Use Biological Materials](#)). Those practices (following [Biosafety in Microbiological and Biomedical Laboratories \[BMBL\]](#), National Institute of Health/Centers for Disease Control and Prevention [NIH/CDC]) must be followed for the storage and use of etiologic agents.

<b>Step 1</b>	The PI/RP ensures his/her staff is trained appropriately and then authorizes and supervises the use of etiologic agents.
<b>Step 2</b>	The PI/RP and staff handle agents based on the characteristics and potential hazards identified during the risk assessment.
<b>Step 3</b>	The PI/R, upon request, informs the Institutional Biosafety Committee (IBC) on the status of regulated etiologic agents so that the IBC can ensure registration with the Centers for Disease Control and Prevention (CDC) or USDA indicates the appropriate status of agents at BNL.

### References

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC)


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## 4. Disposing of Biological Materials

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

### Applicability

This information applies to BNL staff who dispose of biological materials.

### Required Procedure

For the purposes of this subject area, biological wastes include the following:

- All cultures and stocks of biological agents/biologicals (preparations made from living organisms and their products, including vaccines, cultures intended for use in diagnosing, immunizing or treating humans/animals, or in research pertaining thereto);
- Sharps, needles, syringes, scalpels, razor blades, lancets, or glass slides contaminated with biologicals;
- Recombinant DNA;
- Genetically engineered plants and microorganisms;
- Environmental samples (e.g., soil or water) that have been enriched (for microbial growth) or microbially enhanced.

**Biological materials must be disposed of in a manner appropriate to the biohazard.**

Staff perform the following steps when disposing of biological waste.

<b>Step 1</b>	Dispose of nonpathogenic biological liquid and solid waste in regular trash and/or into the sanitary sewer system, according to the <a href="#">Liquid Effluents</a> Subject Area).
<b>Step 2</b>	<p>Chemically disinfect pathogenic biological liquid waste according to <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a>, National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC), and dispose of it into the sanitary sewer system according to the <a href="#">Liquid Effluents</a> Subject Area.</p> <p>There is an existing approval for the discharge of chemically treated (minimum of 10% bleach with a sufficient contact time) pathogenic biologicals into the sanitary system. The use of any other disinfectant besides bleach requires written</p>

	approval from the Environmental Services Division before releasing into the sanitary system, according to the <a href="#">Liquid Effluents</a> Subject Area and via the Experimental Safety Review Process. Contact your <a href="#">Environmental Compliance Representative</a> for assistance.
<b>Step 3</b>	Chemically disinfect pathogenic biological solid waste according to <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a> , National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC), using 10% bleach. However, handle and discard it as a regulated medical waste, according to the <a href="#">Regulated Medical Waste Management</a> Subject Area. For assistance contact the <a href="#">Regulated Medical Waste Supervisor</a> .
<b>Step 4</b>	Decontaminate reusable labware, such as glass flasks, with a chemical disinfectant (such as bleach, as defined in <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a> , National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC).

## References

[Liquid Effluents](#) Subject Area

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), National Institute of Health/Centers for Disease Control and Prevention (NIH/CDC)

[Regulated Medical Waste Management](#) Subject Area


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### Biosafety Organizational Reviews and Approvals

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Point of Contact: [Biosafety Subject Matter Expert](#)

Biosafety Level Facility (BSL)	Agents Approved for Use	Practices	Reviews and Approvals
1	Not known to cause disease in healthy adults	Standard Microbiological Practices	Required Approval <ul style="list-style-type: none"> <li>Department/Division Experimental Safety Review Committee</li> </ul>
2	Associated with human disease. Hazard= percutaneous injury, ingestion, mucous membrane exposure	BSL1 Plus <ul style="list-style-type: none"> <li>Limited access</li> <li>Biohazard warning signs</li> <li>Sharps precautions</li> <li>Biosafety manual/SOPs defining any needed waste decontamination or medical surveillance policies</li> </ul>	Required Approval <ul style="list-style-type: none"> <li>Department Experimental Safety Review Committee</li> </ul> Required For Regulated Agents <ul style="list-style-type: none"> <li>IBC approval</li> </ul> Notify <ul style="list-style-type: none"> <li>Occupational Medicine</li> <li>Emergency Services</li> <li>Security</li> <li>Community Involvement</li> </ul>
3 and 4	There are no approved BSL 3 or 4 facilities at BNL. If you are considering doing work that requires a BSL 3 or 4 Facility, you must obtain approval from the Laboratory Director.		

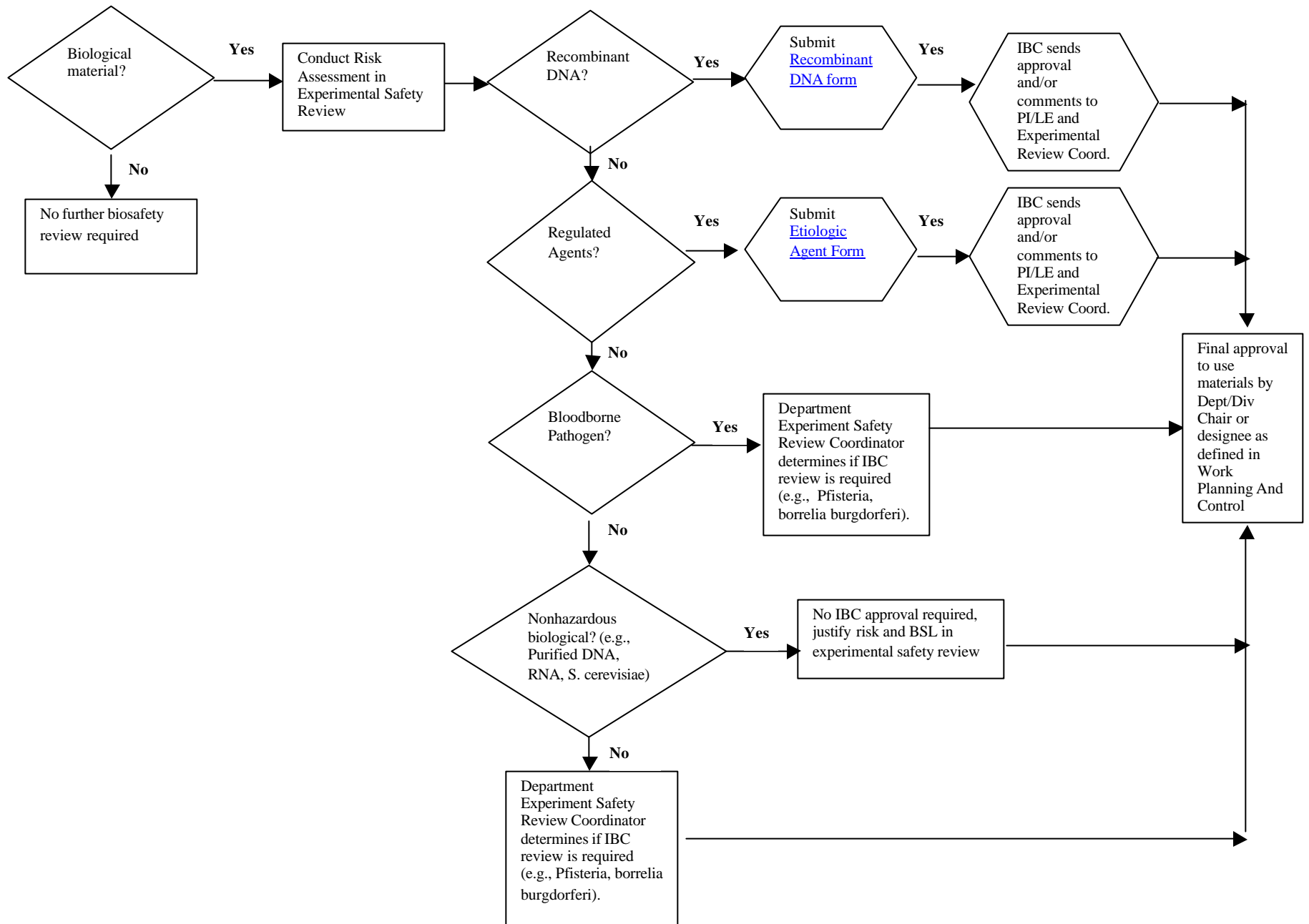
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# Biosafety Review Procedure Flowchart





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### **Special Microbiological Practices for Biosafety Level 2 Microorganisms**

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

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For Biosafety Level 2 work, these required precautions will be taken in addition to practices in the exhibit [Standard Microbiological Practices for Biosafety Level 1 Microorganisms](#). These practices are from the National Institute of Health/Center for Disease Control (NIH/CDC), [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#).

1. Access to the laboratory is limited or restricted by the cognizant space manager when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.
2. The cognizant space manager establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e.g., immunization) may enter the laboratory.
3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.
4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).
5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.
6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the cognizant space manager. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
7. The cognizant space manager ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.
8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels (Follow the [Regulated Medical Waste Management](#) Subject Area):

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
- Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Nondisposable sharps must be placed in a hard-walled container for transport to a processing area for disposal according to the [Regulated Medical Waste Management](#) Subject Area.
- Syringes which re-sheath the needle, needleless systems, and other safety devices are used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.

9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10. Laboratory equipment and work surfaces should be routinely decontaminated with an effective disinfectant, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the cognizant space manager. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.


12. Animals not involved in the work being performed are not permitted in the laboratory.

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### Standard Practices for Biosafety Level 1 Microorganisms

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

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Standard microbiological practices are required as a minimum for work with Biosafety Level 1 Microorganisms. These practices are from the National Institute of Health/Center for Disease Control (NIH/CDC), [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#).

- Access to the laboratory is limited or restricted at the discretion of the cognizant space manager, lab monitor, or principal investigator.
- Persons wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Persons who wear contact lenses in the laboratories should also wear safety glasses and side shields, goggles, or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.
- Mouth pipetting is prohibited; mechanical devices are used.
- All procedures are performed carefully to minimize the creation of the splashes or aerosols.
- Work surfaces are decontaminated at least once a day and after any spill of viable material.
- All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving (see the section [Disposing of Biological Materials](#) for other decontamination and disposal options).
- An insect and rodent control program is in effect.
- Staff will contact their supervisor and report to the BNL Occupational Medicine Clinic if they believe they have been exposed to an infectious biohazard.

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# BNL Institutional Biosafety Committee Etiologic Agent Form

IBC Proposal #

If you plan on working with any of the etiologic agents listed below, please complete entire form and submit to Ann Emrick, Institutional Biosafety Committee (IBC) Coordinator at IBC@bnl.gov. IBC Approval is required before using any of these agents

## Bacterial Agents

- ☐ Acinetobacter calcoaceticus.
- ☐ Actinobacillus-- all species.
- ☐ Actinomycetaceae-- all members.
- ☐ Aeromonas hydrophila.
- ☐ Arachnia propionica.
- ☐ Arizona hinshawii-- all serotypes.
- ☐ **Bacillus anthracis.**
- ☐ Bacteroides spp.
- ☐ Bartonella-- all species.
- ☐ Bordetella-- all species.
- ☐ Borrelia recurrentis, B. vincenti.
- ☐ **Brucella-- all species including B. abortus, B. melitensis, B. abortus, B. melitensis.**
- ☐ **Burkholderia (Pseudomonas) mallei.**
- ☐ **Burkholderia (Pseudomonas) pseudomallei.**
- ☐ Campylobacter (Vibrio) fetus, C. (Vibrio) jejuni.
- ☐ Chlamydia psittaci, C. trachomatis.
- ☐ **Clostridium botulinum, C. chauvoei, C. haemolyticum, C. novyi, C. septicum, C. tetani.**
- ☐ Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pyogenes, C. renale.
- ☐ Edwardsiella tarda.
- ☐ Erysipelothrix insidiosa.
- ☐ Escherichia coli, all enteropathogenic serotypes.
- ☐ **Francisella (Pasteurella) tularensis.**
- ☐ Haemophilus ducreyi, H. influenzae.
- ☐ Klebsiella-- all species and all serotypes.
- ☐ Legionella-- all species and all Legionella-like organisms.
- ☐ Leptospira interrogans-- all serovars.
- ☐ Listeria-- all species.
- ☐ Mima polymorpha.
- ☐ Moraxella-- all species.
- ☐ Mycobacterium-- all species.
- ☐ Mycoplasma-- all species.
- ☐ Neisseria gonorrhoeae, N. meningitidis.
- ☐ Nocardia asteroides.
- ☐ Pasteurella-- all species.
- ☐ Plesiomonas shigelloides.
- ☐ Proteus-- all species.
- ☐ Pseudomonas mallei.
- ☐ Pseudomonas pseudomallei.
- ☐ Salmonella-- all species, serotypes
- ☐ Shigella-- all species, all serotypes
- ☐ Sphaerophorus necrophorus.
- ☐ Staphylococcus aureus.
- ☐ Streptobacillus moniliformis.
- ☐ Streptococcus pneumoniae.
- ☐ Streptococcus pyogenes.
- ☐ Treponema carereum, T. pallidum, and T. pertenu.
- ☐ Vibrio cholerae
- ☐ V. parahemolyticus.
- ☐ **Yersinia (Pasteurella) pestis**
- ☐ Y. enterocolitica.

## Rickettsiae

- ☐ **Coxiella burnetii.**
- ☐ Rickettsia-- all species

## Livestock Pathogens/Toxins

- ☐ African Horse Sickness Virus
- ☐ African Swine Fever Virus
- ☐ Akabane Virus
- ☐ Avian Influenza Virus
- ☐ Blue Tongue Virus
- ☐ Bovine Spongiform Encephalopathy
- ☐ Camel Pox Virus
- ☐ Classical Swine Fever Virus
- ☐ Cowdria Ruminantium
- ☐ Foot and Mouth Disease Virus
- ☐ Goat Pox Virus
- ☐ Japanese Encephalitis Virus
- ☐ Lumpy Skin Disease Virus
- ☐ Malignant Catarrhal Fever Virus
- ☐ Menangle Virus
- ☐ Mycoplasma Capricolum
- ☐ Mycoplasma Mycoides
- ☐ Newcastle Disease Virus
- ☐ Nipah Virus
- ☐ Peste Des Petits Ruminants Virus
- ☐ Rinderpest Virus
- ☐ Sheep Pox Virus
- ☐ Swine Vesicular Disease Virus
- ☐ Vesicular Stomatitis Virus

## Fungal Agents

- ☐ Ascomyces dermatitidis.
- ☐ **occidioides immitis.**
- ☐ Cryptococcus neoformans.
- ☐ Histoplasma capsulatum.
- ☐ Paracoccidioides brasiliensis.

## Viral Agents

- ☐ Adenoviruses--human--all types.
- ☐ Arboviruses--all types.
- ☐ Borna disease A and B viruses--all types.
- ☐ Reutzfeldt--Jacob agent.
- ☐ Cytomegaloviruses.
- ☐ Dengue viruses--all types.
- ☐ **Eastern Equine Encephalitis virus.**
- ☐ **Ebola virus.**
- ☐ Herpesviruses--all types.
- ☐ Nucleopolydnavirus.
- ☐ **quine Morbillivirus.**
- ☐ **antivirus pulmonary syndrome viruses.**
- ☐ Hemorrhagic fever agents including, but not limited to, **Crimean hemorrhagic fever (Congo),** Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
- ☐ Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).
- ☐ Herpesvirus--all members.
- ☐ Infectious bronchitis-like virus.
- ☐ Influenza viruses--all types.
- ☐ Kuru agent.
- ☐ **Lassa virus.**
- ☐ Lymphocytic choriomeningitis virus.
- ☐ **Marburg virus.**
- ☐ Measles virus.
- ☐ Mumps virus.
- ☐ Parainfluenza viruses--all types.
- ☐ Polioviruses--all types.
- ☐ Poxviruses--all members. Rabies virus--all strains.
- ☐ Reoviruses--all types.
- ☐ Respiratory syncytial virus.
- ☐ Rhinoviruses--all types.
- ☐ **Rift Valley fever virus** Exemptions: strain MP-12
- ☐ Rochalimaea quintana.
- ☐ Rotaviruses--all types.
- ☐ Rubella virus.
- ☐ Simian virus 40.
- ☐ **South American Hemorrhagic fever viruses** (Junin, Machupo, Sabia, Flexal, Guanarito)
- ☐ **Tick-borne encephalitis virus complex**, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
- ☐ Vaccinia virus.
- ☐ Varicella virus.
- ☐ **Variola major (Smallpox virus)** and Variola minor viruses.
- ☐ **Venezuelan Equine Encephalitis virus** Exemptions: strain TC-83.
- ☐ Vesicular stomatitis viruses--all types.
- ☐ \*White pox viruses.
- ☐ **Yellow fever virus** Exemption: strain 17-D.

## Recombinant Organisms /Molecules

- ☐ Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this list, or their toxic subunits or other factors known to cause disease (ex. Pili, colonization factors).

Note: Items in these columns listed in bold are CDC Select Etiologic Agents

- ☐ Tetrodotoxin
- ☐ T-2 toxin

## Toxins

- ☐ **Abrin.**
- ☐ **Aflatoxins.**
- ☐ **Botulinum toxins.**
- ☐ **Clostridium perfringens epsilon toxin**
- ☐ **Conotoxins.**
- ☐ **Diacetoxyscirpenol**
- ☐ **Ricin.**
- ☐ **Saxitoxin**
- ☐ **Shigatoxin**
- ☐ **Staphylococcal enterotoxin**

**A. Application Type**

☐ New ☐ Renewal without modifications ☐ Renewal with modifications

**B. Personnel and Project Information**

Principal Investigator:			
Telephone:		Fax:	E-mail:
Department:			
Mail Stop			
Project Title:			

Funding Status:

☐ Internally funded ☐ Seeking External Funding ☐ Externally Funded

Sponsoring Agency(ies): \_\_\_\_\_

List all personnel involved with this project. Include lab technicians, animal handlers, etc. Each employee must initial to indicate they have been informed of potential hazards, safe work practices, availability of medical surveillance, and training related to this project. **Add additional sheets as necessary.**

Employee Name	Employee ID	Position/Title	Citizenship(s)	Experience (A, B, C, D, E)*	Initials

\*Experience:

- A. Prior hands on experience in working with infectious agents (include number of years): \_\_\_\_\_
- B. For Principal Investigator: No prior hands-on experience, but will be collaborating with: \_\_\_\_\_
- C. For Principal Investigator: No prior hands-on experience, but will be receiving training from: \_\_\_\_\_ who does have experience.
- D. For other personnel: No prior hands on experience but will receive training from Principal Investigator.

Please insert below or attach a lay summary of the proposed work. It should be written so that laypersons can understand it. Describe the importance of the research project to the furtherance of biological or medical science. If the project involves infectious material, the summary should emphasize the potential pathogenicity of the microorganisms and recombinants to be used, and the safety precautions to be taken.

**BNL Institutional Biosafety Committee**  
**Etiologic Agent Form**  
**C. Information on Biological Material**

IBC Proposal # \_\_\_\_\_

1. Biological Agent or Toxin: \_\_\_\_\_
2. Specific strains, genotype or CAS number: \_\_\_\_\_
3. Maximum amount to be stored: \_\_\_\_\_
4. Where does this material come from? Provide name of commercial or other source and product number, if applicable. Include quantity to be received. If it is a gift from a collaborator include a statement verifying contents and how it was prepared and how it will be shipped (get approval from BNL Transportation Safety Officer). \_\_\_\_\_  
\_\_\_\_\_
5. Is material a potential pathogen or toxin? ☐ Human ☐ Animal ☐ No  
☐ Risk Group 1: *Agents that are not associated with disease in healthy adult humans.*  
☐ Risk Group 2: *Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.*  
☐ Risk Group 3: *Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk.)*  
For details, see CDC BMBL (<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>) or American Biological Safety Association, Risk Group Classification for Infectious Agents (<http://www.absa.org/riskgroups/index.htm>)
6. Is the agent listed on the CDC List of Select Agents, 42 CFR 72.6, Appendix A? ☐ Yes ☐ No  
For details, see: *CDC Select Agent Transfer Program, Appendix A, List of Select Agents*  
(<http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm#Appendix A>) or see bold agents in list on page 1 of this form.  
If yes, answer the following:
  - a) If you are using a listed agent toxin, does it have an LD50 greater than 100 ng/kg of body weight? ☐ Yes ☐ No
  - b) Is this agent an FDA approved vaccine strain? ☐ Yes ☐ No
7. Are you using recombinant organisms/molecules that are
  - a) Genetically modified microorganisms or genetic elements from organisms listed on the CDC List of Select Agents, Appendix A (or see items that are in bold on page 1 of this form), shown to produce or encode for a factor associated with a disease. ☐ Yes ☐ No
  - b) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in the CDC List of Select Agents, Appendix A, or their toxic subunits. ☐ Yes ☐ NoIf applicable, what is the IBC rDNA Approval number for this protocol? \_\_\_\_\_
8. Does the experiment involve whole animals? ☐ Yes ☐ No  
If yes, what is the IACUC Approval number for this protocol? \_\_\_\_\_
9. Does the experiment involve more than 10 liters of culture? ☐ Yes ☐ No  
Largest volume used is: \_\_\_\_\_ Usual volume used is: \_\_\_\_\_
10. Will radiological material be used in this protocol? ☐ Yes ☐ No  
If yes, what is the RWP number for this protocol? \_\_\_\_\_
11. Will the material be transported on or off BNL site? ☐ Yes ☐ No  
If yes, contact the Transportation Safety Officer or discuss why it is exempt from transportation safety requirements:  
\_\_\_\_\_

**D: Information on Biosafety Level:**

1. Physical Containment Level to be used in this protocol (see table below):      BSL1      BSL 2  
Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment, which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed. See: CDC BMBL, (<http://www.cdc.gov/od/ohs>)

Biosafety Level	Agents	Practices	Safety Equipment	Facilities	Reviews and Approvals
1	Not known to cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required.	Required: Dept. Expt'l safety review Committee Occupational Medicine
2	Associated with human disease. Hazard= percutaneous injury, ingestion, mucous membrane exposure	BSL1 Plus: -Limited access -Biohazard warning signs -Sharps precautions -Biosafety manual/SOPs defining any needed waste decontamination or medical surveillance policies.	Biosafety Cabinet for all manipulations of agents that cause splashes or aerosols of infectious materials. PPE – lab coats, gloves, face protection as needed	BSL1 Plus: - Autoclave available	Required: Dept. Expt'l Safety Review Committee For Select and Etiologic Agents IBC approval Occupational Medicine Notify: Emergency Services Security Community Involvement
3	There are no approved BSL 3 or 4 Facilities at BNL.				

2. Specific laboratory location(s) where this work will occur: \_\_\_\_\_
3. Maximum Amount and specific location will material will be stored: \_\_\_\_\_
4. What type of protective equipment will be used (i.e., type of gloves, lab coat) \_\_\_\_\_
5. For etiologic agents, Occupational Medicine must review and approve use (contact Manager, Occupational Medicine Clinic). Attach the approval notice if applicable.
  - a) Does the work require special medical surveillance?      Yes      No
  - b) Is there a specific vaccine or other preventive pre- or post- exposure treatment recommended or required for work with this agent?      Yes      No
  - c) Will special preparation be required to protect employees, coworkers and/or others in the event of an unplanned release of this agent?      Yes      No
6. Will a Biosafety Cabinet (Tissue Culture Hood) be used for this project:      Yes      No  
If yes, specify location: \_\_\_\_\_
7. Will a Fume Hood be used for this project:      Yes      No  
If yes, specify location: \_\_\_\_\_
8. Will a Cold Room/Environmental Chamber be used for this project:      Yes      No  
If yes, specify location: \_\_\_\_\_
9. Will any biological material used for this project be stored outside of the lab listed above?      Yes      No  
If yes, specify location: \_\_\_\_\_
10. Will there be any transporting of the material on or off-site? (If so, contact the Transportation Safety Officer) \_\_\_\_\_
11. How will the material be disposed of? (Contact your Environmental Compliance Rep for assistance) \_\_\_\_\_

## **E. Compliance with the USA Patriot Act**

### **SEC. 175b. POSSESSION BY RESTRICTED PERSONS.**

- (a) No restricted person described in subsection (b) shall ship or transport interstate or foreign commerce, or possess in or affecting commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent in subsection (j) of section 72.6 of title 42, Code of Federal Regulations, pursuant to section 511(d)(l) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132), and is not exempted under subsection (h) of such section 72.6, or appendix A of part 72 of the Code of Regulations.
- (b) In this section:
- (1) The term 'select agent' does not include any such biological agent or toxin that is in its naturally-occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.
  - (2) The term 'restricted person' means an individual who--
    - (A) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
    - (B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
    - (C) is a fugitive from justice;
    - (D) is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
    - (E) is an alien illegally or unlawfully in the United States;
    - (F) has been adjudicated as a mental defective or has been committed to any mental institution;
    - (G) is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism (<http://www.state.gov/s/ct/rls/pgtrpt/2000/2441.htm>); or
    - (H) has been discharged from the Armed Services of the United States under dishonorable conditions.
  - (3) The term 'alien' has the same meaning as in section 1010(a)(3) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(3)).
  - (4) The term 'lawfully admitted for permanent residence' has the same meaning as in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(20)).
- (c) Whoever knowingly violates this section shall be fined as provided in this title, imprisoned not more than 10 years, or both, but the prohibition contained in this section shall not apply with respect to any duly authorized United States governmental activity.

### **Investigator Assurance of Compliance**

By signing this document, the Principal Investigator accepts responsibility for maintaining full compliance with current CDC Department of Health and Human Services 42 CFR Part 72, *Additional Requirements for Facilities Transferring or Receiving Select Agents*, and confirms that no one will have access to or is working on this project that meets the definition of "restricted person" in the USA Patriot Act.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

# BNL Institutional Biosafety Committee Etiologic Agent Form

IBC Proposal #

## IBC Approval Sheet

**For Interim Approval** (*IBC Chair and whoever he designates for subcommittee review must sign*):

Name	Signature	Date

**Full Committee Approval** (*A quorum will approve and shall consist of a simple majority of the term members (i.e., not including the ex officio members).*)

Name	Signature	Date

## I. Application Type

☐ New    ☐ Renewal without modifications    ☐ Renewal with modifications

## II. Personnel Information

Principal Investigator:			
Telephone:		FAX:	E-mail:
Department:			
Mail Stop:			
Project Title:			

List all personnel involved with this project. Include lab technicians, animal handlers, etc. Each employee must initial to indicate they have been informed of potential hazards, safe work practices, availability of medical surveillance, and training related to this project. *Add additional sheets as necessary.*

Employee Name	Employee ID#	Position/Title	Experience (A, B, C, D, E)*	Initials

\*Experience:

- A. Prior hands on experience in working with recombinant DNA and infectious agents (include number of years)
- B. Prior hands on experience in working with recombinant DNA (include number of years)
- C. For Principal Investigator: No prior hands on experience, but will be collaborating with: \_\_\_\_\_
- D. For Principal Investigator: No prior hands on experience, but will be receiving training from: \_\_\_\_\_ who does have experience.
- E. For other personnel: No prior hands on experience but will receive training from Principal Investigator.

## III. Project Information

**A. Funding Status:** ☐ Internally funded    ☐ Seeking External Funding    ☐ Externally Funded  
Sponsoring Agency(ies): \_\_\_\_\_

**B. Please insert in the box below a lay summary of the proposed rDNA work.** This summary should be written so that laypersons can understand it. Describe the importance of the research project to the furtherance of biological or medical science. The summary must discuss the pathogenicity of the microorganisms and recombinants to be used, the level of risk and the safety precautions to be taken.

#### IV . Information on Biological Material Used for Recombinant DNA Work

**A. . Source(s) and origin of Inserted DNA Sequences** (e.g., mammalian, prokaryotic, non mammalian eukaryotic and vendor or other source.):

**B. Biological function of the Inserted DNA Sequence(s):**

**C. Vectors(s) to be Used:**

**D. Host(s) to be Used:**

**E. Will you attempt to obtain expression of a foreign gene?**

☐ No      ☐ Yes

If yes, identify the protein to be produced:

## V. Experiment Category

Experiment Categories are presented in increasing order of complexity. **Check all that apply** to your recombinant DNA experiments:

### ☐ **Exempt Experiments (refer to NIH Guidelines, Section III-F)**

The following recombinant DNA molecules are considered exempt from the NIH Guidelines.

- ☐ F1 *Those that are not in organisms or viruses.*
- ☐ F2 *Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.*
- ☐ F3 *Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.*
- ☐ F4 *Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).*
- ☐ F5 *Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.*
- ☐ F6 *Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment as follows:*
  - a. *Cloning of DNA that is not a pathogen or known oncogene, in E. coli K-12, S. cerevisiae, or B. subtilis host-vector systems.*
  - b. *Introduction into cultured cells of any recombinant DNA containing less than half of a eukaryotic viral genome (with the exception of RG 2, 3 or 4 pathogens)*
  - c. *Purchase or transfer of transgenic rodents.*

### ☐ **Experiments that Require IBC Notification Simultaneous with Initiation of the Experiment (refer to NIH Guidelines, Section III-E)**

- ☐ 1. *Experiments involving the formation of rDNA molecules containing more than two-thirds of the genome of any eukaryotic virus.*
- ☐ 2. *Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of rDNA into the germ-line (transgenic rodents).*

### ☐ **Experiments that Require Local (IBC) Approval before Initiation (refer to NIH Guidelines, Section III-D)**

- ☐ 1. *Experiments Using Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 agents) as Host-Vector Systems*
- ☐ 2. *Experiments in Which DNA From Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 Agents) is Cloned in Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.*
- ☐ 3. *Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems*
- ☐ 4. *Recombinant DNA Experiments Involving Whole Animals: This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms (including viruses) tested on whole animals.*
- ☐ 5. *Recombinant DNA Experiments Involving Whole Plants*
- ☐ 6. *Experiments involving more than 10 liter of culture*

### ☐ **Experiments that Require Federal (NIH) RAC and Local (IBC) Approval before Initiation (refer to NIH Guidelines, Section III-B)**

- ☐ 1. Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight. Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules.
- ☐ 2. Certain human gene transfer experiments that are considered 'Minor Actions', and qualify for an accelerated review.
- ☐ 3. Minor modifications to human gene transfer experiments (i.e., does not significantly alter the basic design of the protocol and does not increase risk to human subjects or the environment.)

☐ **Experiments that Require Federal (RAC, NIH) and Local (IBC) Approval before Initiation (refer to NIH Guidelines, Section III-A)**

- ☐ 1. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such an acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
- ☐ 2. Certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects, which are considered "Major Actions".

☐ **Experiments not included in any of the above categories.**

Describe:

If you plan and have checked **only** Exempt Experiments, sign here and submit (you do not have to complete the next part of the form):

---

Signature

Date

## For Non-Exempt Experiments:

**VI . Information on containment to be used:** The IBC and the NIH Guidelines require that the Principal Investigator make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines.

**A. Biological Containment:** In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant or animal cell) in which the vector is propagated in the laboratory will be considered together. The combination of vector and host should be chosen so that the following types of 'escape' are minimized: (i) survival of the vector in its host outside the laboratory, and (ii) transmission of the vector from the propagation host to other non-laboratory hosts.

☐ **Uncertified Host-Vector System 1:** Host-Vector systems that have not been certified by NIH include BL21 and its derivatives. *E. coli* K-12 strains are at least H-V1 (see below).

**H-V1 and H-V2 Host-Vector Systems:** These systems have been certified by NIH to provide different levels of biological containment. For guidance, see NIH Guidelines, Appendix E. Certified host-vector systems ([http://www4.od.nih.gov/oba/rac/guidelines\\_02/appendix\\_e.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/appendix_e.htm)) Appendix I. Biological containment ([http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_I.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_I.htm))

☐ **H-V1:** Host-Vector 1 systems provide a moderate level of containment. Specific certified H-V1 systems are:

- The following plasmids are accepted as the vector components of certified *B. subtilis* systems: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223, and pAB124. *B. subtilis* strains RUB 331 and BGSC 1S53 have been certified as the host component of Host-Vector 1 systems based on these plasmids.
- The following specified strains of *Neurospora crassa*, which have been modified to prevent aerial dispersion: In1 (inositol-less) strains 37102, 37401, 46316, 64001, and 89601. Csp-1 strain UCLA37 and csp-2 strains FS 590, UCLA101 (these are conidial separation mutants). Eas strain UCLA191 (an "easily wettable" mutant).
- The following *Streptomyces* species: *Streptomyces coelicolor*, *S. lividans*, *S. parvulus*, and *S. griseus*. The following are accepted as vector components of certified *Streptomyces* Host-Vector 1 systems: *Streptomyces* plasmids SCP2, SLP1.2, pIJ101, actinophage phi C31, and their derivatives.
- *Pseudomonas putida* strains KT2440 with plasmid vectors pKT262, pKT263, and pKT264.

☐ **H-V2:** Host-Vector 2 systems provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be  $<1/10^8$  under specified conditions.

### B. Select what Risk Group is the material in:

- ☐ Risk Group 1: Agents that are not associated with disease in healthy adult humans.
- ☐ Risk Group 2: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
- ☐ Risk Group 3: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk.)

For details, see

- CDC BMBL (<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>)
- American Biological Safety Association, Risk Group Classification for Infectious Agents (<http://www.absa.org/riskgroups/index.htm>)

**C. Select Physical Containment Level to be used in this protocol:**

☐ BSL1 (For Risk Group 1) ☐ BSL 2 (For most Risk Group 2 and some 3)

Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment, which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed. For additional guidance, see NIH Guidelines, Appendix G. Physical containment, [http://www4.od.nih.gov/oba/rac/guidelines\\_02/appendix\\_g.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/appendix_g.htm)) or CDC BMBL, <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
1	Not known to cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required.
2	Associated with human disease. Hazard= percutaneous injury, ingestion, mucous membrane exposure	BSL1 Plus: -Limited access -Biohazard warning signs -Sharps precautions -Biosafety manual/SOPs defining any needed waste decontamination or medical surveillance policies.	Biosafety Cabinet for all manipulations of agents that cause splashes or aerosols of infectious materials. PPE – lab coats, gloves, face protection as needed	BSL1 Plus: - Autoclave available
3 and 4	There are no BSL 3 or 4 Level Facilities at BNL; contact the IBC for further guidance.			

**Investigator Assurance of Compliance**

By signing this document, the Principal Investigator accepts responsibility for maintaining full compliance with current NIH Guidelines in the conduct of the research described in this application, including [Section IV.B.7, Roles and Responsibilities of the Principal Investigator](#).

Signature

Date

**The following is to be completed by the Institutional Biosafety Committee:**

### Review and Approval Documentation:

Date reviewed by committee \_\_\_\_\_


Review process: email meeting (for email review, copies of emails are attached)

This project should be approved as written

\_\_\_ This project requires the following modifications/clarifications (include any medical surveillance requirement):

**Signature for approval. All remaining action items will be resolved by the IBC Coordinator with concurrence by the IBC Chair. There are no issues that are open that should prevent the approval:**

[illegible]



Forms

Contact List

BMB Instructions

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## Definitions: Biosafety in Research

Effective Date: **December 2002**

Point of Contact: [Biosafety Subject Matter Expert](#)

Term	Definition
biological material	Include preparations made from living organisms (e.g., humans, plants, animals, bacteria) and their products (e.g., cells, proteins, blood, DNA, RNA) regardless of their pathogenicity.
biological waste	<ul style="list-style-type: none"> <li>• All cultures and stocks of biological agents/biologicals (preparations made from living organisms and their products, including vaccines, cultures intended for use in diagnosing, immunizing or treating humans/animals, or in research pertaining thereto);</li> <li>• Sharps, needles, syringes, scalpels, razor blades, lancets, or glass slides contaminated with biologicals;</li> <li>• Recombinant DNA;</li> <li>• Genetically engineered plants and microorganisms;</li> <li>• Environmental samples (e.g., soil or water) that have been enriched (for microbial growth) or microbially enhanced.</li> </ul>
biological risk assessment	An assessment of risk that focuses primarily on preventing laboratory-associated infections and includes factors such as pathogenicity, route of transmission, infectious dose, agent stability, concentration, and origin of material. For more details see the National Institute of Health/Center for Disease Control (NIH/CDC), <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a> .
Biosafety Level	Combination of laboratory practices, containment equipment, and special laboratory design made to achieve different levels of physical containment defined as Biosafety Levels 1-4. See the National Institute of Health/Center for Disease Control (NIH/CDC), <a href="#">Biosafety in Microbiological and Biomedical Laboratories (BMBL)</a> .
bloodborne pathogen	Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
etiologic agent, nonregulated	A viable microorganism or its toxin, which causes, or may cause, human disease but is not listed in 42 CFR 72 (e.g., <i>Pfisteria</i> , scrapie).
etiologic agent, regulated	A viable microorganism or its toxin, which causes, or may cause, human disease as listed in 42CFR 72 (see DHHS CDC Etiologic Agent Reporting Form) or USDA High Consequence Livestock Pathogens and Toxins.
Experiment Review Coordinator (ERC)	Assigned by the Department Chair/Division Manager. The ERC is the person (or persons) within the Department/Division who assists the Principal Investigator/Responsible Person in generating Experimental Safety Reviews and also coordinates the review of experiments. ERCs are members of the Experimental Safety Review Committee (ESRC). The ERC serves as the interface between the operational groups and the experimental groups, and the ESRC and

	between the operational groups and the experimental groups, and the ESRC and the experimental groups.
Experimental Safety Review Committee (ESRC)	<p>A Departmental/Divisional level committee with the responsibility for reviewing experiments (and significant modifications to experiments) for the following:</p> <ul style="list-style-type: none"> <li>• ES&amp;H concerns;</li> <li>• Ensuring appropriate controls for each experiment (during set-up, operations, and tear-down) are established;</li> <li>• Based upon ES&amp;H concerns, recommending to the Department/Division approval or disapproval.</li> </ul> <p>Some Departments/Divisions may already have existing committees or committees with multiple responsibilities that may also perform the Experimental Safety Review. There is no need to change the make up or names of these committees; however, for consistency, ESRC will be used in this Subject Area. In cases where the scope and hazard levels are sufficiently low, an appropriately sized subcommittee of the ESRC may be used.</p>
Principal Investigator/Responsible Person (RP)	The Principal Investigator (PI), alternately, Responsible Person (RP), is that person who takes the responsibility for all the members of a team that carry out an experiment or experimental program at Brookhaven National Laboratory. PI/RPs may or may not be employees of BNL, but they are able to act as the spokesperson for their experiment.
Recombinant DNA	<p>Recombinant DNA is defined as either</p> <p>(a) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or</p> <p>(b) molecules that result from the replication of those described in (a). See the <a href="#">NIH Guidelines for Research Involving Recombinant DNA Molecules</a>.</p>
select agent	<p>A microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of 42 CFR Part 72. The term also includes</p> <p>(1) Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease; and</p> <p>(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A , or their toxic subunits.</p>

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**Revision History: Biosafety in Research**

Point of Contact: [Biosafety Subject Matter Expert](#)

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## Revision History of this Subject Area

Date	Description	Management System
December 2002	This subject area describes the procedures users of biological materials must follow to perform research at BNL. In this subject area, biological materials include human and primate blood, blood components or tissue, microorganisms, bacteria, protozoa, mycoplasma, viruses, and other potentially infectious material such as recombinant DNA. This subject area also serves as an essential component of the BNL work planning and control requirements for work with biological materials.	Worker Safety and Health

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